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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,253	RASTELLI ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed August 28, 2002 in Paper No. 7 is acknowledged and has been entered.

2. Claims 1-19 are pending in the application and are currently subject to the following restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-6, insofar as the claims are drawn to a method for diagnosing harmartoma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for diagnosing harmartoma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for diagnosing harmartia, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for diagnosing harmartia, Applicants must do so by particularly identifying one or a specific plurality of more

than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for diagnosing renal carcinoma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for diagnosing renal carcinoma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for diagnosing malignant angiomyolipoma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for diagnosing malignant angiomyolipoma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for diagnosing hypomelanotic macule, wherein said method comprises measuring the

expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for diagnosing hypomelanotic macule, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for diagnosing facila agniofibroma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for diagnosing facila agniofibroma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for diagnosing shagreen patches, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for diagnosing shagreen patches,

Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for diagnosing ungula fibroma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for diagnosing ungula fibroma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to harmartoma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to harmartoma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to harmartia, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to harmartia, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to renal carcinoma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to renal carcinoma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to malignant angiomyolipoma, wherein said method comprises measuring the expression of one or more nucleic acid

molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to malignant angiomyolipoma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to hypomelanotic macule, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to hypomelanotic macule, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to facila agniofibroma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to facila agniofibroma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to shagreen patches, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to shagreen patches, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to ungula fibroma, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 1-6, insofar as the claims are drawn to a method for determining the susceptibility to ungula fibroma, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from

the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 1-6 are to be drawn.

Claim 7, insofar as the claim is drawn to a method for treating a tuberous sclerosis complex associated disorder in a subject, wherein said method comprises administering to the subject an agent that modulates the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, which cannot be classified because the biologic and chemical nature of the recited agent is unspecified.

Note: If Applicants wish to elect one of the inventions of claim 7, insofar as the claim is drawn to a method for treating a tuberous sclerosis complex associated disorder in a subject, wherein said method comprises administering to the subject an agent that modulates the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claim 7 is to be drawn.

Claim 7, insofar as the claim is drawn to a method for treating a tuberous sclerosis complex associated disorder in a subject, wherein said method comprises administering to the subject an agent that modulates the activity of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, which cannot be classified because the biologic and chemical nature of the recited agent is unspecified.

Note: If Applicants wish to elect one of the inventions of claim 7, insofar as the claim is drawn to a method for treating a tuberous sclerosis complex associated disorder in a subject, wherein said method comprises administering to the subject an agent that modulates the activity of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claim 7 is to be drawn.

Claims 8 and 9, insofar as the claims are drawn to a method for identifying a candidate therapeutic agent for treating a tuberous sclerosis complex associated disorder in a subject, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified, for example, in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claims 8 and 9, insofar as the claims are drawn to a method for identifying a candidate therapeutic agent for treating a tuberous sclerosis complex associated disorder in a subject, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 8 and 9 are to be drawn.

Claim 10, insofar as the claim is drawn to a method for assessing the efficacy of a treatment for a tuberous sclerosis complex associated disorder in a subject, wherein said method comprises measuring the expression of one

or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified, for example, in class 435, subclass 6.

Note: If Applicants wish to elect one of the inventions of claim 10, insofar as the claim is drawn to a method for assessing the efficacy of a treatment for a tuberous sclerosis complex associated disorder in a subject, wherein said method comprises measuring the expression of one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, Applicants must do so by particularly identifying one or a specific plurality of more than one nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claim 10 is to be drawn.

Claims 11-14, insofar as the claims are drawn a nucleic acid molecule comprising a polynucleotide sequence selected from the group consisting of TSC 1-8, 10-12, and 15-142, a pharmaceutical composition comprising said nucleic acid molecule, a vector comprising said nucleic acid molecule, and a cell comprising said vector, classified in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325+, respectively.

Note: If Applicants wish to elect one of the inventions of claims 11-14, Applicants must do so by particularly identifying one nucleic acid molecule selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claims 11-14 are to be drawn.

Claim 15, insofar as the claim is drawn a polypeptide encoded by a nucleic acid molecule comprising a polynucleotide sequence selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 530, subclass 350.

Note: If Applicants wish to elect one of the inventions of claim 15, Applicants must do so by particularly identifying one nucleic acid molecule selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claim 15 is to be drawn.

Claim 16, insofar as the claim is drawn an antibody that binds specifically to a polypeptide encoded by a nucleic acid molecule comprising a polynucleotide sequence selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 530, subclass 387.1.

Note: If Applicants wish to elect one of the inventions of claim 16, Applicants must do so by particularly identifying one nucleic acid molecule selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claim 16 is to be drawn.

Claim 17, insofar as the claim is drawn a kit that detects two or more of the polynucleotide sequences selected from the group consisting of TSC 1-8, 10-12, and 15-142, which cannot be classified because the biologic and chemical nature of the components of the kit are not specified.

Note: If Applicants wish to elect one of the inventions of claim 16, Applicants must do so by particularly identifying two or more polynucleotide sequences selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claim 17 is to be drawn.

Claim 18, insofar as the claim is drawn an array that detects one or more of the polynucleotide sequences selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 422, subclass 82.08.

Note: If Applicants wish to elect one of the inventions of claim 18, Applicants must do so by particularly identifying one or more polynucleotide sequences selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claim 18 is to be drawn.

Claim 19, insofar as the claim is drawn a plurality of nucleic acid comprising one or more of the nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, classified in class 536, subclass 23.1.

Note: If Applicants wish to elect one of the inventions of claim 19, Applicants must do so by particularly identifying one or more nucleic acid molecules selected from the group consisting of TSC 1-8, 10-12, and 15-142, to which claim 19 is to be drawn.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of claim(s) 11-14, 15, 16, 17, 18, and 19 are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct.

The inventions of claim(s) 1-6, 7, 8 and 9, and 10 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct.

The inventions of claim(s) 11-14, 15, 16, 17, 18, and 19 and of claim(s) 1-6, 7, 8 and 9, and 10 are not at all related because the products of claim(s) 11-14, 15, 16, 17, 18, and 19 are not specifically used in any of the steps of the claimed methods of claim(s) 1-6, 7, 8 and 9, and 10.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their

different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Claim 1 is a linking claim. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

(703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

STEPHEN RAWLINGS

slr
October 20, 2003